

REMARKS

The Office Action of August 9, 2006 has been carefully considered.

Objection has been raised to the claims on the basis of the use of the term "preferably" and an error in claim 7. The claims have now been amended to remove "preferably" and to correct the error.

Claims 1, 3, 4-5, 7-8, 10, 12, 17 and 19-20 have been rejected under 35 USC 112, 2nd paragraph.

In claim 1, "said bearing element" (line 14) finds antecedent basis on lines 6-7.

Claim 1 has been amended to provide a basis for "said contact zone" throughout the claims.

Claims 4, 7, and 8 have been amended to remove the cited objections.

Claim 20 now depends from claim 18, providing antecedent basis for the second spacer element.

The "broad and narrow" ranges have been canceled.

Withdrawal of this rejection is requested.

Claims 1, 3 15 and 21 have been rejected under 35 USC 102(b) over Hayhurst.

According to the invention, the inventors have discovered that one of the difficulties in tying knots in suture thread lies in the need for the surgeon to exert tension on the thread, firstly in order to tighten the suture prior to making a permanent connection between the two strands of thread, and secondly to make it easier to tie the knot. One difficulty thus lies in the need for the surgeon to control the tension to be exerted on the thread in order to avoid tightening excessively, or conversely tightening insufficiently, which in both cases would lead to a suture that is ineffective. Controlling thread tension and tying the knots themselves are

both acts that are difficult since they need to be done using pliers that are long (20 to 30 cm), through trocars, and in a space that is confined. Excessively tightening the threads can lead to a thread itself breaking or to pinching of the biological tissue that is to be repaired. Such pinching can lead to phenomena of tissue rupture or of inflammatory reaction. In contrast, when tightening is not sufficient, the junction between pieces of tissue or between a tissue and a prosthesis can be imperfect and the suture is not leak tight.

The prior art proposes various devices enabling two strands of thread to be connected and blocked together instead of requiring the surgeon to tie knots. Nevertheless, in those prior art devices, it is always necessary to put the thread under tension in order to tighten the suture before connecting and blocking the two strands of thread together. During this step, it is not possible for the tension exerted on the thread by the surgeon to be controlled automatically in any way.

The present invention provides a suture device comprising blocking means for connecting together two strands of thread in a blocking zone, and controlled tensioning means for controlled tensioning of the thread, and suitable, after the two strands of the thread have been blocked together using the blocking means, for exerting tension on the thread at a first predetermined tension value.

In the device of the invention, the blocking means and tensioning means cooperate so that two strands of suture thread are blocked together before exerting a first predetermined tension value, and once the two strands have been blocked together, the device tensions the suture threads at the first predetermined tension value in automatic manner.

Tensioning the suture thread in this manner enables the two pieces of tissue, or a piece of tissue and a prosthesis,

that are to be united by the suture to be moved together effectively by tightening the thread. With prostheses, the tissue can be biological or artificial.

As mentioned in the present specification on page 4 lines 31-37, the term "controlled tensioning" in claim 1 is used herein to mean tensioning at a first known and predetermined tension value, can be applied automatically using the tensioning means, and no longer depends on the initial tension exerted manually by the surgeon on the thread or on a device; that is why the device of the invention is said to be "semiautomatic." Thus, the first predetermined tension value can be lower or greater, but is preferably lower than the tension which would be exerted by the surgeon on the thread prior to blocking (see page 6, lines 6-11).

It is submitted that the device of Hayhurst is a clip which only enables two strands of thread to be connected and blocked together instead of requiring the surgeon to tie knots as the above mentioned prior art. There is no means for controlling the tensioning of the threads after their blocking, which is the basis of the invention.

The device of Hayhurst is only capable of maintaining the sutures firmly pinched after the blocking. The tension value on the strands depends on the value of the tension exerted by the surgeon before the blocking, and more precisely the tensioning after blocking is necessarily equal or close to the initial tension before blocking. If the blocking has been done without prior tensioning of the thread by the surgeon, the clip of Hayhurst will never exert a tensioning force.

As evidence of this, see the following passages in Hayhurst:

- column 1 lines 43-46: "The clip is slidable along the suture from a remote location to a suturing site. With the

clip at the suturing site, the suture is tensed and the clip is closed against the suture to securely fasten the suture at the site."

- column 3 lines 13-15: "Once in position at the suturing site, the suture is tensed and the clip is closed."

It is submitted that the Office Action is incorrect in asserting that the clip of Hayhurst comprises "controlled tensioning means suitable for exerting a tension having a first predetermined tension value after the two strands of said thread have been blocked with the junction between said bearing element and said blocking zone of the device being provided by said controlled means."

First, in view of the above mentioned definition of the "predetermined tension value," it is submitted that the clip device of Hayhurst does not comprise controlled tensioning means for exerting such a predetermined tension value. However, to more clearly distinguish the claimed invention from the Hayhurst device, claim 1 has been amended to recite "at a predetermined tension value *independent from the tension exerted on the threads before the blocking thereof.*"

Second, as to the hinge 123 of the clip of Hayhurst, which the Office Action alleges to read on the claimed "controlled tensioning means" of the invention, this hinge does not exert a tensioning on the threads. Indeed, as mentioned in Hayhurst:

column 3, lines 21 et seq: "...as the upper leg 21 is forced toward the lower leg 22, the first prong 24 and second prong 25 are deflected toward one another as the opening 27 is slid over the curved tops of the hooks. Once the hooks 29 and 30 extend through the opening 27, the prongs 24 and 25 snap apart so that the hooks 29 and 30 extend partly over the outer surface 31 of leg 21 near the opening 27, thereby locking the

clip 20 in the closed position."

- column 3, lines 40-42 and 54-55: "The plastic material provides the resiliency for urging the clip 20 into the open position... The hinge 123 biases the clip 12 into the V-shaped open position (FIG. 5)."

In fact, the blocking (and alleged tensioning) is exerted by hooks or other means distinct from the hinge which maintain the two legs closed despite the force exerted by the hinge tending to open the legs.

Further, the clip of Hayhurst does not itself exert a tensioning on the threads, but only a compression for blocking them in the absence of initial tensioning on the threads by the surgeon.

Accordingly, Applicants submit that the disclosure of Hayhurst does not anticipate the device of claim 1.

Turning to claim 3, the Office Action states that:

- the device of Hayhurst in its open configuration holds the suture together at a tension that is low and in its closed configuration holds the suture at a first predetermined tension value, and

- Hayhurst discloses an initial distance in which two ends of suture can be blocked together with the thread being at a tension, and a final distance for exerting a controlled tension having a first predetermined tension value.

In fact, contrary to what is stated, the device of Hayhurst in its open configuration does not hold the sutures together, and therefore does not exert a low tension on the threads.

The initial distance and final distance claimed in claim 3 are distances between the blocking zone and the contact zone. The predetermined tension value corresponds to a variation of the distance between two parts of the device

corresponding to said blocking zone and said contact zone.

As explained on page 25 of the present specification, two situations can arise while the surgeon is putting the suture device into place:

1) When blocking is triggered, the tension being exerted by the surgeon on the suture threads is equal to T_1 where $T_1 < T_0$ (T_0 = the first predetermined tension value, e.g. 2 N), and the length of the strands of thread between the contact zone and blocking zone is L . In this first situation, when tensioning is triggered after blocking has taken place, the device is no longer held by the placing instrument 1₂ and seeks to expand since it is subjected only to the action of the tension T_1 in the threads, so the distance extending between said contact zone 4₁ and said blocking zone 4₂ will take on a value greater than L , i.e. $L + b$. The tension exerted on the suture threads by the device is then equal to T_0 as the device can't expand beyond the distance $L + b$, where b corresponds to the extent to which the threads lengthen under the effect of the difference in tension $T_0 - T_1$.

2) When blocking is triggered, the tension exerted by the surgeon on the suture threads immediately prior to blocking is equal to $T_1 > T_0$ and the length of the strands of thread between the contact zone and blocking zone is L .

When, after blocking, tensioning of the threads by the device is triggered, the device will compress under the action of the tension T_1 in the threads, and the distance between the contact zone and blocking zone will take on a value that is less than L , i.e. $L - b$, where $b < a$. The tension exerted by the device on the threads is thus equal to T_0 and the device prevents from compressing beyond the distance $L - b$, where b corresponds to the shortening of the distance under the effect of the difference in tension $T_1 - T$.

However, in Hayhurst, the distance between the contact zone 316 and the blocking zone does not vary. After the blocking, there is no variation of the distance between two parts of the device and no variation of the tensioning of the threads by any controlled tensioning means. There is a variation of the distance between the two legs and possibly variation of the tensioning between before and after the blocking of the threads, but not between an initial stage just after blocking and a later final stage after blocking, as in the claimed invention.

In Hayhurst, hinge 123 does not form the junction between the bearing surface 316 and the blocking zone 330, but hinge 123 does form a junction between the two parts of the blocking means, namely legs 121 and 122. In fact the hinge is more comparable to the resilient connecting means of the two jaws of the blocking means recited in present claim 18 rather than any tensioning means between the blocking and contact zones.

Accordingly, the device of Hayhurst cannot be read on claim 3. However to more clearly distinguish the claimed invention from the Hayhurst device, claim 3 has been amended to recite that the variation of the distance occurs *after blocking*.

With regard the claim 15, is noted that the Office Action states that Hayhurst discloses that the closing of the device in the blocking position triggers the tensioning of the thread and a user can exert the threads at a desired tension by triggering the tensioning of the threads by the device after blocking at the same desired tension. However, as already discussed, in Hayhurst the tensioning exerted by the device is always identical to the tensioning initially exerted by the user; the tension exerted by the device is not controlled by the device itself. This device does not comprise any

controlled tensioning means so as to exert "said predetermined tension value *independent from the tension exerted on the threads before the blocking thereof.*"

By contrast, as recited in the present claims, the point of the invention is that the tensioning of the threads after blocking is controlled by the device and is independent of the initial tension exerted by the user.

Withdrawal of this rejection is requested.

Claims 2, 8 and 17 have been rejected under 35 USC 103(a) over Hayhurst in view of Dakin et al, claims 4-7, 12 and 13 have been rejected under 35 USC 103(a) over Hayhurst in view of Rubricius, and claim 9 has been rejected under 35 USC 103(a) over Hayhurst in view of Egan et al.

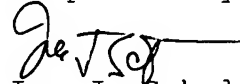
These secondary references have been cited to show aspects of the claimed embodiments. However, none of these further documents discloses or suggests a device for blocking the threads of a suture with means for exerting on the threads after blocking a predetermined tension value *independent from the tension exerted on the threads before the blocking.*

Withdrawal of these rejections is requested.

The allowability of claims 10, 11, 14, 18 and 20 has been noted.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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